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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,484	09/30/1999	JAN WADSTEIN	NATNUT-03972	6938

7590 06/26/2007  
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SAN FRANCISCO, CA 94105

EXAMINER
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ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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06/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/410,484

Applicant(s)

WADSTEIN ET AL.

Examiner

Ernst V. Arnold

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 4/27/07 has been entered.

Claims 4-6 have been cancelled. Claims 8 and 10-18 have been withdrawn. Claims 1-3, 7 and 9 are under examination.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646) in view of Kawamura et al. (Hypertension 1996, 27, 408-413) and Shinitzky et al. (US 4,474,773).

Applicant claims a method of treating hypertension in humans.

**Determination of the scope and content of the prior art  
(MPEP 2141.01)**

Cook et al. disclose a method of reducing body fat comprising the administration of a safe and effective amount of conjugated linoleic acid (Abstract and claims 1-9). Cook et al. define conjugated linoleic acid as including mixtures and salts thereof (Column 4, lines 21-26). Cook et al. disclose 9,11-octadecadienoic acid and 10,12-octadecadienoic acid as conjugated linoleic acids obtained by their methods and therefore reading on instant claim 3 (Column 4, lines 37-41 and 60-67). Other geometric isomers, including cis-9, cis-11, can be obtained consequently reading on instant claim 2 (Column 4, lines 48-59 and column 5, lines 3-8)). Cook et al. disclose the addition of 0.1 to 10 grams of conjugated linoleic acid to the diet of humans as a food supplement thus reading on instant claim 9 (Column 2, example 3). Since the material was ingested, then the conjugated linoleic acid was administered orally and therefore reads on instant claim 7.

Kawamura et al. provide a nexus teaching between hypertension, weight loss and decreases in blood pressure. Kawamura et al. teach that changes in body weight exhibited significant correlations with blood pressure reduction in

hypertensive overweight human patients (Abstract, pages 1 and 2; page 9, final paragraph).

Shinitzky et al. teach methods of treating warmblooded mammals comprising administering a pharmaceutically effective amount of a composition comprising 5-10% linoleic acid for the treatment of hypertension (Claims 1, 4 and 24).

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

Cooke et al. do not expressly teach a method of treating hypertension in humans.

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a hypertensive human patient with the conjugated linoleic acid method of Cooke et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Cooke et al. provide a method of reducing body fat and Kawamura et al. teach that reduction in weight in hypertensive patients results in a lowering of blood pressure. Furthermore, Shinitzky et al. provide the teaching that linoleic acid (C18:2, cis-9, cis12) can be used to treat hypertension. Since conjugated linoleic acid is a mixture of positional and geometrical isomers of linoleic acid, then one of ordinary skill in the art would immediately envision conjugated linoleic acid in the treatment of hypertension. In fact, similar properties may normally be

presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Thus, the method of Cooke et al. is beneficial to the instantly claimed patient population and would have been obvious to one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that the claims are not obvious because the cited references do not provide: 1) no way to predict whether a given agent will cause hypertension, prevent hypertension or be nonactive with respect to hypertension without testing the substance and 2) do not provide a reasonable expectation of

success. The Declaration of Asgeir Saebo has been fully considered by the Examiner. Mr. Saebo correctly points out that ephedrine can cause weight loss but also increase hypertension thus establishing that not all agents that cause weight loss can have a positive effect on hypertension. In other words, weight loss itself may not be enough to have a beneficial effect on hypertension because of the type of agent used in the weight loss. Mr. Saebo continues to state that how conjugated linoleic acid works in the body is complex and "it is not scientifically valid to draw a conclusion that because an agent causes weight loss it can also be expected to decrease hypertension." These are strong arguments.

However, the Examiner cannot agree. First, Kawamura et al. provide a nexus teaching between weight loss in hypertensive patients and lowering of blood pressure. Cook et al. provide a method of reducing body fat, which is weight loss. Shinitzky et al. teach linoleic acid in the treatment of hypertension. The art recognizes linoleic acid in a method of treating hypertension. (See also pertinent art below.) Therefore, it remains obvious to one of ordinary skill in the art that the method of Cook et al. can lower blood pressure via administration of conjugated linoleic acid because the positional and geometrical isomers of linoleic acid would be expected to have similar properties to linoleic acid in the absence of evidence to the contrary. One of ordinary skill in the art would have a reasonable expectation of success because the art teaches administration of linoleic acid for the treatment of hypertension.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP63036744 (English language Abstract: DERWENT-ACC-NO: 1988-087068) teaches a composition containing linoleic acid and linolenic acid used for preventing allergosis, thrombosis and hypertension.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

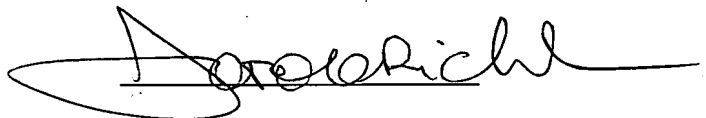
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Application/Control Number: 09/410,484

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
Art Unit 1616  
May 02, 2006

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized flourish underneath.

Johann Richter  
Supervisory Patent Examiner  
Technology Center 1600

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